

## **REMARKS**

### **STATUS OF THE CLAIMS**

Claims 1-40 and 43-51 were pending. As shown above, claims 1 and 27 have been amended as suggested by the Examiner to reinsert "Pol" to clarify the nature of the HIV polypeptide encoded by the claimed sequences. As this term was present in the originally filed claims, no new matter has been added and entry of the amendments is respectfully requested. Thus, claims 1-40 and 43-51 are pending as shown above.

### **PRIORITY**

The Examiner asserts that claims 1-40 and 43-51 are not entitled to priority to any of 09/475,704; 60/114,495; and/or 60/152,195 on the grounds that these applications do not provide written support for SEQ ID NO:30-32. (Office Action, pages 2-3).

Applicants again respectfully disagree with the Examiner's assertion regarding priority, namely that the priority applications set forth the particularly claimed sequences. While a claim to the benefit of an earlier application requires that the disclosure in the earlier application comply with 35 U.S.C. § 112, first paragraph, compliance with 112, 1<sup>st</sup> paragraph does not necessarily require that the priority applications set forth *in ipsis verbis* the terms and language recited in the claims. *See, e.g., In re Lukach*, 169 USPQ 795, 796 (CCPA 1971).

The Examiner's asserts that it is sufficient to show that SEQ ID NOs:30-33 are not literally present in the priority applications. However, literal support is not required to establish compliance with 35 U.S.C. § 112. Applicants submit that the skilled artisan would recognize that all three priority applications describe and enable production of synthetic polynucleotide sequences encoding an HIV polymerase (*see, e.g.*, page 4, lines 10-15, page 10, lines 21-26, Example 1 and Section 2.1.2 (starting on page 28) of 09/475,704; page 5, lines 6-14, page 14, lines 5-14; and page 38, lines 4-13 of 60/152,195; and page 36, lines 1-4 of 60/114,495).

Thus, Applicants submit that Applicants are entitled to an effective filing date of the 09/475,704; 60/114,495; and 60/152,195 applications.

### **CLAIM OBJECTIONS**

Applicants thank the Examiner for the careful attention paid to the claim numbering and acknowledge that because claim 47 depends from dependent claim 2, that the claims will have to renumbered when allowed.

**REJECTIONS WITHDRAWN**

Applicants note with appreciation that all the rejections under 35 U.S.C. §§ 112, second paragraph, 102 and 103 have been withdrawn.

**NEW REJECTIONS – 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, WRITTEN DESCRIPTION AND ENABLEMENT**

The previously withdrawn rejections under 35 U.S.C. § 112, 1st paragraph (written description and enablement) have been re-instated. (Office Action, pages 3-4). In support of this reversal, the Examiner states:

...upon further consideration of the claims being amended in the response filed on 10/18/04 to recite a genus of HIV polypeptides (instead of HIV Pol polypeptides) that elicits a Pol-specific immune response, the claims are broader than what was previously claimed. Thus, 112, first paragraph rejections of the instant claims follows.

Applicants respectfully submit that it is improper for withdrawn rejections to be reiterated when **no** amendments affecting § 112 were made to the claims after the rejections had already been withdrawn.

In the instant case, the rejections under 35 U.S.C. § 112, 1<sup>st</sup> paragraph were withdrawn after the Office fully considered the subject matter of claims reciting an “HIV polypeptide.” *See*, Office Action mailed on August 8, 2005 in which the Examiner stated on the record that the §112, 1st paragraph (written description and enablement) rejections were withdrawn. *See*, Office Action mailed 8/9/05, pages 22-23, emphasis added:

Applicant’s arguments, see pages 8-11, filed 5/16/05, with respect to 112 first paragraph written description **have been fully considered and are persuasive.** The rejection of claims 1-40 and 47 has been withdrawn because the instant polynucleotide sequences recite a structure and function and that function can tolerate many modifications and the structure of an HIV Pol is well known in the prior art as stated in the Declaration filed by Dr. Donnelly filed 9/8/03.

Applicant’s arguments, see pages 8-11, filed 5/16/05, with respect to 112 first paragraph enablement **have been fully considered and are persuasive.** The rejection of claims 1-40 and 47 has been withdrawn because several polynucleotide sequences comprising a nucleotide sequence encoding an HIV Pol polypeptide were well known in the art at the time the invention was made (See, U.S. Patent No. 6,602,705 and prior art rejections of record and the skilled artisan can make a sufficient number of species to represent the genus of polynucleotide sequences (See Declarations of Record, filed 9/8/03 and 12/27/02).

No amendments affecting § 112 were made in the amendment filed on December 9, 2005. Thus, it is improper to now reiterate previously withdrawn rejections.

In any event, Applicants have amended the claims as shown above to return to the original claim language specifying that the HIV polypeptides encoded by the claimed sequences are HIV *Pol* polypeptides (see, original claim 1). Since the Office has acknowledged that the as-filed specification describes and enables the claimed genus of HIV Pol polypeptide-encoding sequences, the (improperly) re-instated written description and enablement rejections have been obviated. See, Office Action mailed August 9, 2005, pages 22-23, reproduced above, and page 5 of the Office Action mailed February 15, 2006 acknowledging that

[t]he specification contemplates production of a genus of a polynucleotide sequence encoding an immunogenic HIV [Pol] polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO:30, 31 or 32. The as-filed specification provides sufficient description of an immunogenic HIV Pol polypeptide as set forth in SEQ ID NO:30, 31, or 32.

Therefore, in view of the foregoing amendments, the written description and enablement rejections may be properly withdrawn.

#### **PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING**

Applicants request the provisional double patenting rejection over 10/190,435 be held in abeyance until indication as to allowable claims is received in one of the applications.

**CONCLUSION**

In view of the foregoing amendments, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.


The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §1.16, §1.17, and §1.21, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648, referencing Atty. Docket No. 2302-1631.20.

Please direct all further written communications regarding this application to:

Helen Lee  
NOVARTIS VACCINES AND DIAGNOSTICS, INC.  
Intellectual Property - R440  
P. O. Box 8097  
Emeryville, CA 94662-8097  
Telephone: (510) 923-2192  
Facsimile: (510) 655-3542.

Respectfully submitted,

Date: July 17, 2006

By:   
Dahna S. Pasternak  
Attorney for Applicants  
Registration No. 41,411

NOVARTIS VACCINES AND DIAGNOSTICS, INC.  
Intellectual Property - R440  
P. O. Box 8097  
Emeryville, CA 94662-8097  
Telephone: (510) 923-2192  
Facsimile: (510) 655-3542